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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. FSIS-2012-0028]

RIN 0583-AD51

Eligibility of Namibia to Export Meat Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

Action: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to add Namibia to the list of countries whose meat inspection system is equivalent to the system that the United States has established under the Federal Meat Inspect Act (FMIA) and its implementing regulations. FSIS's review of Namibia's laws, regulations, and inspection implementation show this to be the case.

At this time, because Namibia advised FSIS that it intends to export only boneless (not ground) raw beef products, such as primal cuts, chuck, blade, and beef trimmings to the United States, FSIS has only assessed Namibia's inspection system with respect to beef. Thus, should this rule become final, Namibia would need to submit

additional information for FSIS to review before FSIS would allow Namibia to export product from other types of livestock to the U.S. All products that Namibia exports to the U.S. will be subject to re-inspection at United States ports of entry by FSIS inspectors.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0028. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

DOCKET: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend its meat products inspection regulations to add Namibia to the list of countries eligible to export meat products to the United States (9 CFR 327.2(b)). Namibia is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Under the FMIA and the regulations that implement it, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 620). The FMIA also requires that the livestock from which such imports are produced be slaughtered and handled in connection with slaughter in a manner that is consistent with the Humane Methods of Slaughter Act (7 U.S.C. 1901-1906). Section 327.2 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export meat and meat products to the United States.

Paragraph 327.2(a) of 9 CFR requires that a foreign country's meat inspection system provide standards equivalent to those of the United States and provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem inspection, humane methods of slaughter and handling, and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national

government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering and preparation of product by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the FMIA and its implementing regulations (9 CFR 327.2(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue

standards; and (7) any other inspection requirements (9 CFR 327.2(a)(2)(i)).

A foreign country's inspection system must be evaluated by FSIS before eligibility to export meat and meat products to the United States can be granted. This evaluation consists of two processes: A document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. FSIS requests that countries provide information about their inspection systems through its self-reporting tool (SRT). The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems. Through the SRT, FSIS collects information on practices and procedures in six areas, known as equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document

review is satisfactory, an onsite review is scheduled using a multidisciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview>.

The FMIA and implementing regulations require that foreign countries be listed in the CFR as eligible to export meat and meat products to the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to export meat or meat products to the United States are listed in the meat inspection regulations at 9 CFR 327.2(b). Once listed, the government of an eligible country must certify to FSIS that establishments that wish to export meat products to the United States are operating under requirements equivalent to those of the United States (9 CFR 327.2(a)(3)). Countries must renew certifications of establishments annually (9 CFR 327.2(a)(3)).

Section 20 of the FMIA (21 U.S.C. 620) prohibits the importation into the United States of adulterated or misbranded carcasses, parts of carcasses, meat, or meat

products of amenable species that are capable of use as human food. To verify that products imported into the United States are not adulterated or misbranded, FSIS reinspects and randomly samples those products at ports of entry, before they enter U.S. commerce.

Evaluation of the Namibian Meat Inspection System

In 2002 and again in 2005, the government of Namibia requested approval to export meat (beef) products to the United States. Namibia stated that, if approved, its immediate intent was to export boneless (not ground) raw beef products such as primal cuts, chuck, blade, and beef trimmings to the United States.

In 2006, FSIS conducted a document review of Namibia's meat (slaughter and processing) inspection system to determine whether that system is equivalent to the United States' meat inspection system. FSIS concluded, on the basis of that review, that Namibia's laws, regulations, control programs, and procedures were sufficient to achieve the level of public health protection required by FSIS.

Accordingly, FSIS proceeded with an on-site audit of Namibia's meat inspection system from September 25 to October 11, 2006, to verify whether Namibia's central competent authority (CCA) in charge of food inspection

effectively implemented a meat inspection system equivalent to that of the United States. FSIS concluded that Namibia's meat inspection system did not meet the equivalence components for government oversight, statutory authority and food safety regulations, sanitation, HACCP, and chemical residue and microbiological testing programs. For example, FSIS found that the CCA did not have adequate administrative controls over the inspection system and lacked a training program to maintain the competency of the inspection personnel and laboratory analysts. Namibia did not provide direct and continuous inspection by the assigned government inspectors. Additionally, the sanitation programs at the establishments visited by the audit team lacked measures to prevent recurring deficiencies that could result in direct product contamination or adulteration, and inspectors did not identify the problems.

Following the 2006 on-site audit, Namibia provided a corrective action plan that addressed FSIS's findings. Namibia also implemented comprehensive inspection training programs on requirements consistent with FSIS requirements for all its inspection and laboratory personnel.

From September 2 to 9, 2009, FSIS conducted a follow-up on-site audit to determine whether the outstanding issues identified during the previous on-site audit had been resolved. The 2009 audit identified new systemic deficiencies within the equivalence components for government oversight, sanitation, HACCP, chemical residue, and microbiological testing programs. Specifically, the 2009 audit found that Namibia did not have a plan to continuously analyze and implement staffing requirements in order to provide relief staff assignments during planned and unplanned field inspection personnel absences. In addition, Namibia did not effectively require that establishments maintain sanitation programs to prevent insanitary conditions and product contamination. Namibia also did not provide effective verification to ensure HACCP plans were effectively implemented and did not provide adequate control over laboratory quality systems.

Following the 2009 on-site audit, Namibia again provided a comprehensive corrective action plan that addressed the findings identified. FSIS reviewed the corrective action plan and concluded that Namibia had satisfactorily addressed all the 2009 audit findings. In addition, FSIS concluded that Namibia's corrective action

plan satisfactorily addressed all the previous 2006 audit findings.

In 2013, FSIS conducted an initial equivalence follow-up on-site audit of Namibia's meat inspection system and verified that Namibia had satisfactorily implemented the corrective action plans proffered in response to the 2009 on-site audit. In 2013, the FSIS audit identified new findings within the equivalence components of government oversight, statutory authority and food safety regulations, sanitation, and chemical residue testing programs. The audit found that although the CCA had implemented all corrective action plans related to government oversight, it was unable to provide any record to demonstrate that the inspection personnel at the local establishments were properly implementing and documenting inspection procedures. Additionally, inspection personnel were including non-compliance findings on the Inspection Verification Activities Sheet instead of using a separate non-compliance record (NR) form to document non-compliance findings. Regarding statutory authority and food safety regulations, Namibia had implemented all related corrective action plans but could not demonstrate that it had adequate records to verify that establishments met Specified Risk

Materials (SRM) requirements, to enforce SRM requirements, and to prevent potential SRM contamination from cattle 30 months of age or older. The CCA also had not effectively implemented its verification procedures for sanitation performance standards and was unable to demonstrate how it assessed its residue plan results. Namibia's National Residue Program did not have sampling plan procedures or strategies for dealing with residue violators.

In response to the 2013 audit findings, Namibia implemented immediate corrective actions and submitted another corrective action plan that addressed the findings identified during the audit of its food safety system. FSIS reviewed Namibia's corrective action plan and concluded that Namibia had satisfactorily addressed 2013 audit findings. FSIS conducted another audit in 2014 to verify that Namibia had effectively implemented those corrective actions.

On the basis of the 2014 follow-up on-site audit, FSIS has concluded that Namibia has fully implemented the corrective action plan that it had submitted in response to the 2013 audit. FSIS did not find any significant problems during the audit. Furthermore, through the audit, FSIS found that Namibia has implemented a sampling and testing

program for Shiga toxin-producing Escherichia coli (STEC) that is equivalent to FSIS's program. Therefore, FSIS has determined that the CCA has adequately addressed all previous audit findings and met FSIS equivalence criteria related to all six components.

In summary, FSIS has completed the document review, on-site audits, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has determined that, as implemented, Namibia's inspection system (slaughter and processing) with respect to beef is equivalent to the United States' meat inspection system. The final 2009, 2013, and 2014 audit reports on Namibia's meat inspection system (slaughter and processing) can all be found on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

Should this rule become final, Namibia will be eligible to export to the U.S. boneless (not ground) beef raw products such as primal cuts, chucks, blade, and beef trimmings. The government of Namibia will need to certify to FSIS that those establishments that wish to export beef or beef products to the United States are operating in

accordance with requirements equivalent to those of the United States. FSIS will verify that the establishments certified by Namibia's government meet the United States requirements through periodic and regularly scheduled audits of Namibia's meat inspection system.

If this proposed rule is adopted, the beef products that Namibia exports to the United States will be subject to re-inspection at the U.S. ports-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. Moreover, even though a foreign country may be listed in FSIS regulations as eligible to export to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of APHIS' regulations, which also regulate the export of meat products from foreign countries to the United States.

In the future, if Namibia wants to export other meat products to the U.S. (e.g., pork products), it will need to notify FSIS and submit information about its requirements and inspection program for these products. FSIS would then review the information and determine whether the Agency needs to audit the operations in Namibia producing these

products to determine whether the requirements and inspection program for these products is equivalent to those in the U.S. Namibia would not be allowed to export additional products to the U.S. until FSIS determines that the country's requirements and inspection program for the products are equivalent to FSIS's system.

In addition, FSIS will conduct other types of re-inspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis for the detections of drug and chemical residues, pathogens, species, and product composition. Products that pass re-inspection will be stamped with the official United States mark of inspection and allowed to enter United States commerce. If they do not meet United States requirements, they will be refused entry and within 45 days must be exported to the country of origin, destroyed, or converted to animal food (subject to approval of the U.S. Food and Drug Administration (FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phs-import-component/phs-implementation-letter-to-importers/ct_index.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been designated a “non-significant” regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Economic Impact Analysis for Namibia Export Equivalence

This proposed rule would add Namibia to the list of countries eligible to export meat products into the United States. The government of Namibia intends to certify only one Namibian establishment as eligible to export boneless raw beef products to the United States. Given this establishment’s beef production capacity and the projected export volume, FSIS projects that this rule, if implemented, will not have an impact on the United States economy. The annual boneless beef production of this establishment averaged 21.4 million pounds from 2008 to 2014. The projected volume of export to the United States is about 1.9 million pounds in 2015, increasing to about 12.5 million pounds in 2019.¹ The average annual United States domestic beef production in 2012-2014 was 25.3 billion pounds, projected to be 24.2 billion pounds in

¹ According to Namibia, this is the “optimistic” projection they wish to achieve. Market conditions will affect actual results.

2015.² The total United States import of beef averages 2.47 billion pounds per year for 2012-2014, projected to be 2.91 billion pounds in 2015.³ Therefore, the projected Namibia beef imports in 2015 would only be about 0.007% of total U.S. production and 0.07% of total U.S. imports. If Namibia achieves the projected export goal in 2019 and assuming that United States beef production and import volume stay about the same, the projected beef imports from Namibia would still only be about 0.05% of total U.S. production, and 0.5% of total U.S. imports.

Although Namibia indicates that, for now, it is seeking to export boneless beef products only, this would not preclude it from exporting other meat products in the future, provided that the products meet all FSIS and APHIS requirements and any additional requirements that FSIS might have in place with regard to the products. Therefore, the long-term economic impact could be larger than what we can assess right now.

Effect on Small Entities

The FSIS Administrator has made a preliminary determination that this proposed rule will not have a significant impact

² http://www.ers.usda.gov/media/1823699/rmpfore_apr-2015_r.xls, accessed on May 8, 2015; part of *Livestock, Dairy, & Poultry Outlook* at Economic Research Service, USDA.

³ Ibid.

on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). As mentioned above, the expected trade volume is very small. Therefore, the proposed action should have no significant impact on small entities that produce beef products domestically.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of

the United States. FSIS provided Namibia with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0094. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this proposal and will announce it on-line through the FSIS Web page located at:

[http://www.fsis.usda.gov/regulations & policies/Proposed Rules/index.asp](http://www.fsis.usda.gov/regulations%20&%20policies/Proposed%20Rules/index.asp).

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies,

procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Director, Office of Adjudication
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Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

List of Subjects in 9 CFR Part 327

Imports, Meat Inspection

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 327 as follows:

Part 327-IMPORTED PRODUCTS

1. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 327.2 [Amended]

2. Amend §327.2 by adding Namibia in alphabetical order to the list of countries in paragraph (b).

Done at Washington, DC on September 14, 2015.

Alfred V. Almanza,
Acting Administrator.

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